UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **WAVE ONE TVT, TVT-O and TVT-S CASES LISTED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF ANNE WILSON, MBA[1]

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this reply memorandum in support of their motion [Dkt. 2083] to exclude the opinions and testimony of Plaintiffs' designated expert Anne Wilson.

I. ARGUMENT

A. The Fact That Audits Capture A "Snapshot In Time" Is Not An Adequate Basis For Completely Ignoring The Audit Findings That Were Contrary To Ms. Wilson's Opinions

Ms. Wilson's threshold opinion concerning each of TVT, TVT-O, and TVT-S is that at the time when each of these devices was first marketed Ethicon had failed to comply with the then-applicable industry standards for design controls and risk analysis. That is, her threshold opinion for each device is based on a particular snapshot in time. Yet Plaintiffs' Response to Ethicon's motion attempts to justify Ms. Wilson's failure to consider the work and findings of independent auditors for the reason that these audits cover a "specific snapshot in time." Pltfs.' Resp. [Dkt. 2166] at 6. It is worth mentioning again that Ms. Wilson admits Ethicon would not

[1] Ex. A is a list of the cases to which the motion to exclude Anne Wilson applies. Unless otherwise noted, all exhibits referenced herein are attached to the motion.

have been permitted to obtain the CE mark for these devices unless independent auditors found full compliance with the applicable design control and risk analysis standards at the very same snapshot in time that is at the core of each of her opinions. Ex. E, Wilson 9/17/15 Dep. Tr. 175:22-176:22. Plaintiffs' Response does not dispute that the independent audit findings are entirely contrary to Ms. Wilson's opinions. Yet Ms. Wilson's report, her testimony, and the Plaintiffs' Response provide no adequate explanation for why Ms. Wilson disagrees with the independent audit findings.

Plaintiffs argue that Ms. Wilson's failure to consider important independent audit findings concerning Medscand's and Ethicon's compliance with the very same standards on which she relies is mere fodder for cross-examination. However, this Court has excluded expert opinions in cases where significant study findings exist contrary to the expert's opinions and the expert's report fails to provide adequate explanation for disagreement with the studies. *Trevino v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 56538, at *23-25 (S.D. W. Va. Apr. 28, 2016).

B. Ms. Wilson's Opinions Are Indeed Based On European Regulatory Standards

Plaintiffs' Response states that "[a]t her deposition in the *Mullins* case, Ms. Wilson was explicit that her opinions were not based on *any* regulatory standards." Pltfs.' Resp. [Dkt. 2166] at 7. This statement is absolutely false. In fact, the testimony cited and quoted as support for the statement has nothing to do with the statement. *Id*.[2] Ms. Wilson has plainly admitted that all of the standards on which she relies, including ISO 13485 and ISO 14971, are in fact developed and adopted in Europe as regulatory standards. Ex. E, Wilson 9/17/16 Dep. Tr. 96:22-102:24.

[2] Ms. Wilson's testimony that she "did not look at any regulatory *submission* documents" has nothing to do with the question whether her opinions are "*based on*" regulatory standards. Regulatory "submission" documents would be documents in the 510(k) application process. Ms. Wilson testified that she did not review those "submissions." The standards she attempts to apply are, however, regulatory standards.

C. Plaintiffs Tacitly Acknowledge That There Were No Design Control And Risk Management Standards Applicable To The Design And Development Of TVT

Plaintiffs' Response does not dispute that the design of TVT had been completed by 1995. Plaintiffs' Response [Dkt. 2166] cites Ms. Wilson's report for the proposition that "ISO 13485 has defined the requirements for proper risk analysis in the medical device industry since 1996." Pltfs.' Resp. [Dkt. 2166] at 9. However, Plaintiffs did not even respond to Ethicon's explanation in its initial memorandum that (1) ISO 13485:1996 was not even released until December 1996, more than a year after the TVT design had been completed, (2) Ms. Wilson admits that she cannot say that ISO 13485 was ever a recognized standard until the 2003 edition was issued, and (3) ISO 13485 on its face plainly does not specify "requirements for proper risk analysis."

Plaintiffs say that "Ms. Wilson does not intend to retroactively apply standards," but rather "she is simply explaining how Ethicon's conduct in the original design . . . of the TVT device measures against standards and industry practices existing at the time of that conduct." Pltfs.' Resp. [Dkt. 2166] at 9. This is classic doubletalk. As if to justify Ms. Wilson's opinions, Plaintiffs go on to make the amazing argument that "Ms. Wilson's opinions in this case are not based solely on industry standards," but rather "are built upon her professional knowledge . . . ." *Id*. The Court should not allow this *ipse dixit*. Moreover, Ms. Wilson's reports plainly state that her opinions are based on ISO standards. Nevertheless, if Plaintiffs want her to go beyond any formal industry standards as the basis for her opinions, then Ms. Wilson was required to come forward and explain that basis in detail in her reports, *see* Fed. R. Civ. P. 26(a)(2)(B)(i), so that both Ethicon and the Court could evaluate whether that basis meets *Daubert*'s standards.

D. Ms. Wilson's Opinions Are Not Reliable Because She Did Not Consider All Of The Documents Available And Because She Is Not Qualified To Evaluate Many Of These Documents

As explained in Ethicon's initial memorandum, Ms. Wilson's ultimate, broad opinion is that there is an absence of evidence: that she does not see documentation that Ethicon fulfilled requirements of risk management standards. *See, e.g.*, Ex. B, Wilson Report at 3 ("I reviewed the initial design documents prepared by Medscand and Ethicon in connection with my work in this case. Ethicon's design documentation for the TVT-R, as outlined in the Design History File (DHF), does not provide evidence that the TVT-R complies with Quality Management System (QMS) requirements for the design of a medical device."). Ethicon explained a litany of critical risk management compliance documents concerning TVT, TVT-O, and TVT-S that Ms. Wilson has never considered. Plaintiffs' Response does not dispute that Ms. Wilson failed to consider the many documents discussed in Ethicon's initial memorandum, but rather Plaintiffs shrug it off and argue that these oversights should only go to the weight of Ms. Wilson's opinions and should be left for cross-examination.

They cite this Court's statement that "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other 'sufficient facts or data' to support her opinion." Pltfs.' Resp. [Dkt. 2166] at 12 (citing *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 U.S. Dist. LEXIS 59047, at *55 (S.D. W. Va. May 6, 2015)). However, this statement actually explains why Ms. Wilson's opinions concerning Ethicon's risk analyses and ongoing risk management should be excluded. Again, Ms. Wilson broadly opines that she does not see that Ethicon documented its compliance with risk management standards. Having ignored the relevant documents, Ms. Wilson's opinions are not based on "sufficient facts or data." Ms. Wilson's opinions are nothing more than *ipse dixit*

since she failed to consider the very documents that demonstrate Ethicon's compliance with the industry risk management standards on which she relies.

Ethicon explained in its initial memorandum that Ms. Wilson admitted at her deposition that she is not qualified to evaluate Ethicon's clinical expert reports, clinical evaluation reports, and risk/benefit analyses – i.e., the very documents that housed much of Ethicon's ongoing risk management that she opines is missing. Plaintiffs' Response does not dispute this argument, and Ms. Wilson's opinions should be excluded for this additional reason.

E. Plaintiffs Failed To Respond To Ethicon's Argument Concerning Ms. Wilson's Opinions Regarding Its TVT-O Risk Analysis

Ethicon explained in its initial memorandum that Ms. Wilson's opinions concerning the TVT-O should be excluded for the additional reason that she failed to apply the ISO 14971 mandate to rely on prior risk analyses on components that have already undergone risk analysis. Plaintiffs failed to respond to this argument. Thus, Plaintiffs have failed in their burden to demonstrate the reliability of Ms. Wilson's opinions that the TVT-O risk analysis was deficient, and, thus, her opinions regarding same should be excluded.

F. Plaintiffs Fail To Qualify Ms. Wilson As An IFU Warnings Expert

Ethicon's initial memorandum explained that Ms. Wilson's credentials do not indicate any expertise in drafting an IFU or product warnings. Plaintiffs responded by improperly attempting to place the burden on Ethicon to prove she is not qualified. That is, they argue "Ethicon failed to verify at Ms. Wilson's deposition whether her professional experience includes IFUs or product warnings." Pltfs.' Resp. [Dkt. 2166] at 16. It is not Ethicon's burden to prove that Ms. Wilson is unqualified, but rather Plaintiffs' burden to come forward with evidence that she is qualified.

Plaintiffs' Response did not challenge Ethicon's argument that Ms. Wilson's credentials fail to show her as having any expertise in the area of IFUs or product warnings. Instead, Plaintiffs argue that product warnings are part of the overall risk management process and *ergo* she should be allowed to testify. However, this argument ignores the fact that ISO 14971 specifically calls for many different types of expertise to participate in risk management:

> **A.2.3.3 Qualification of personnel**
>
> It is most important to get people with the expertise necessary to perform risk management tasks. The risk management process requires people with expertise in areas such as:
>
> — how the medical device is constructed;
>
> — how the medical device works;
>
> — how the medical device is produced;
>
> — how the medical device is actually used;
>
> — how to apply the risk management process.
>
> In general, this will require several representatives from various functions or disciplines, each contributing their specialist knowledge. The balance and relation between individuals performing risk management tasks should be considered.

Ex. H, ISO 14971:2007 at 18. It would be a giant leap to assume that Ms. Wilson is an expert of IFUs and product warnings merely because she is somewhat familiar with ISO 14971.

IV. CONCLUSION

For all of these reasons, Ms. Wilson's opinions are irrelevant, unreliable, beyond the scope of her qualifications, and should be excluded from the trial of this matter.

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: ***Mullins, et al. v. Ethicon, Inc., et al.*** ***Case No. 2:12-cv-02952***	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, William M. Gage, certify that I have this day electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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